

application is respectfully requested in view of the claim amendments provided hereinabove, the newly added claims and the remarks provided hereafter.

Claims 1-15 were rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 5,655,537 (Crowley). Crowley discloses a device for making Doppler measurements and imaging within a body fluid conduit. According to the patent, the device is capable of making imaging and Doppler measurements from substantially the same location at substantially the same time, and can allow highly accurate blood flow volume measurements to be made easily and in a short time. The device includes a catheter 2 and a control system 4. The catheter has a disposable catheter sheath 6 including a rotatable ultrasonic transducer 8 driven by a high fidelity flexible drive shaft 10. According to the patent, a distal end of the catheter sheath, corresponding to the location of the transducer, is constructed from an acoustically transmissive material, such as low-density polyethylene. The flexible nature of the sheath is indicated in Fig. 1.

The present invention is directed to a Doppler probe for detecting or measuring blood flow in a vessel. A key feature of the invention lies in the use of a shapeable portion (16 in Fig. 1) that allows a physician to generally customize the configuration of the distal device that is introduced into the patient. The shapeable portion is plastically deformable immediately prior to or during the medical procedure, or in other words, it is capable of holding its new shape as it is being manipulated within the patient. If necessary, the shapeable portion should be capable of being further plastically manipulated to assume additional new shapes as needed during the course of a normal medical procedure. See, e.g., page 9 lines 3-19 of the present application.

As stated in the application, there are many ways of making a portion of the probe shapeable. One example is including an outer sheath that is made of a malleable material.

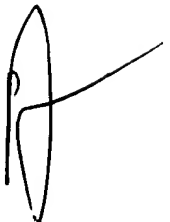


The malleable material may comprise a piece of annealed metal. Annealing makes the metal tubing ductile, and thus, able to accept a new shape by the minimal application of manual pressure. In addition to annealed stainless steel, any other suitable metal, metal-polymer composite, or other material can be used that is sufficiently malleable to be able to be plastically reconfigured to a desired shape. See, e.g., page 9, line 20 to page 10, line 16.

Independent claim 1 has been amended to specify that the shapeable material is plastically deformable. As such, when the material is plastically deformed immediately prior to, or during the procedure, it generally holds its new shape as it is being manipulated within the patient. The Crowley disclosure does not teach such a plastically deformable device. Although the Crowley patent is short on details in this regard, it appears that the Crowley catheter sheath is flexible (low-density polyethylene), indicating that it does not hold the shape into which it may be manipulated. Flexible probes cannot generally be controlled sufficiently to be able to assuredly place the transducer at a particular site. The shortcomings of flexible probes are discussed in the Background section of the present application. Accordingly, since the flexible portion in Crowley is not shapeable (plastically deformable), Applicants respectfully submit that claim 1 is not anticipated by Crowley.

Claims 2-15 are dependent upon claim 1, and include all of its limitations, including the limitation of a plastically deformable shapeable portion as discussed above. Accordingly, Applicants respectfully submit that these claims are also allowable over Crowley.

Claims 16-20 were rejected under 35 USC §103(a) as being unpatentable over Crowley in view of Nicholas et al. Claim 16 has been amended to specify that the

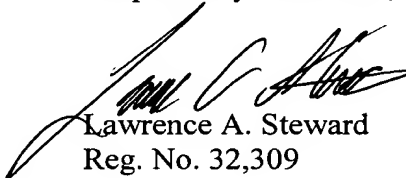


shapeable portion is capable of retaining a formed shape as the probe is manipulated within the bodily passage. As stated above, Crowley does not teach or suggest a shapeable portion capable of retaining its shape. Nicholas et al was cited for teaching the use of a multiple electrical connector. Nicholas also does not teach or suggest a shapeable portion capable of retaining its shape. Therefore, Applicants respectfully submit that claims 16-20 are allowable over the cited art.

New claims 22-24 have been added to the case to incorporate additional details relating to the shapeable portion. These details are also not disclosed in the cited art. Therefore, Applicants respectfully submit that these new claims are also allowable.

Based on the foregoing, Applicants respectfully request that all claims 1-24 are in condition for allowance, and action toward that end is respectfully requested. If the Examiner believes that prosecution of this application may be advanced by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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Marked up copy of claims:

1. (Amended) A medical probe for detecting flow of fluid within a bodily passage, the probe having a distal end and comprising:

a transducer head that includes an ultrasonic transducers adjacent the distal end of the probe, the ultrasonic transducers adapted for generating signals in response to fluid flow;

an electrical conductor operatively connected to the ultrasonic transducer and connectable to an external source unit for processing flow-responsive signals; and

a shapeable portion extending proximally from adjacent the distal end, said shapeable portion being plastically deformable.

2. (Amended) The medical probe of claim 1, wherein the shapeable portion comprises a metal cannula [adapted to be plastically deformed].

10. (Amended) The medical probe of claim 9, wherein the first and second wires include shapeable wire [such that the first and second wires are adapted to comprise the shapeable the portion of the medical probe].

16. (Amended) A medical probe for detecting flow of fluid within a bodily passage, the probe having a longitudinal axis and comprising:

a transducer head that includes an ultrasonic transducer having a first operative surface;

an electrical conductor, comprising two wires, each having a first end and a second end, the first ends being operatively connected to the ultrasonic transducer, and

the second ends being connectable to an external source unit adapted to generate and process Doppler signals;

a handle portion;

an outer sheath connected to the handle portion and at least partially houses the electrical conductor, the distal portion of the outer sheath, which extends distally from the handle portion, at least partially comprising a shapeable portion [with the shapeable portion] having a distal end, the shapeable portion being capable of retaining a formed shape as the probe is manipulated within the bodily passage; the transducer head being affixed about the distal end of the shapeable portion.